

510(k) Summary

Submitted by:

DePuy Orthopaedics, Inc.

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Fax: (305) 269-6441

Contact Person:

Suzana Otaño, Project Manager, Regulatory Affairs

Date Prepared:

January 31, 2012

General Provisions

The names of the devices are:

Proprietary Name	Common or Usual Name	
Multiple	Bone Fixation Plates, Intramedullary Nails, Pins, Wires,	
	Screws and Washers	

Name of Predicate

Devices

The devices are substantially equivalent to their currently marketed versions.

The predicate devices are listed below.

Classification

HRS, HWC, HTN, KTT, LXT, HSB, JDW, HTY

Performance Standards

Performance standards have not been established by the FDA under section 514

of the Food, Drug and Cosmetic Act for these devices.

Device Description

This submission covers an update to the sterilization parameters of DePuy Orthopaedics' range of metallic internal fracture fixation devices manufactured from Titanium, Stainless Steel and Cobalt Chrome and include the following. No modifications have been made to the devices and they are identical to their predicates.

K103408, K101421, K082300 Anatomic Locked Plating System K093474, K091294 Fracture, LCL and Fusion Plating Systems

K101240 ALPS Small Bone Locked Plating System K090877 Proximal Tibia Locking Plating System

K090492, K083364, K081546 Small Bone Locking Plating System

K090374 Sterile DVR

K083843 Locking Anatomic and Composite Plating System

K072832 Anterolateral and Medial Locking Plating System

K072423 4.5mm Locking Broad & Narrow Compression Plates

K072083 Small Fragment Locking Plating System

K061748 Fragment Plate System

K060969 Polyax Locked Plating System

K050932 Distal Volar Radius Anatomical Plate System

K111663

K003235 PERI II Knee Fracture System

K993465, K981775 Calcaneal Peri-Articular Plate

K990392 DePuy ACE Spider Plate

K990120 DePuy ACE TiMax Medial Pilon Plate

K983853 DePuy ACE TiMAX Meta Plate

K972629 DePuy ACE TK2 Hip Screw System

K970503, K950618, K813554 DePuy Ace Trochanteric Side Plate, Supracondylar

Plate, Captured Hip Screw

K930592 Universal Reconstruction Plate

K920738 ACE 100 Degree Tubular Plate

K905774 Titanium Mini-Plating System

K905595 ACE Reconstruction Plate

K060864 Multidirectional Threaded Peg

K954485 6.5mm solid cancellous bone screw

K926047 8.0mm cannulated cancellous bone screw

K903811 ACE cannulated cortical bone screw

K903810 ACE cannulated self tapping cancellous bone screw

K874670 ACE Cannulated Self-Tapping cortical bone screw

K872859 Cancellous bone screw

K895107 Washers

K042325 ACE Trochanteric Nail

K033878 Universal Humeral Nail

K033806 Proximal Humeral Nail

K033329 Universal and Troch Entry Nails

K032097 Tibial Nail

K023115 VersaNail TTC Fusion Nail

K003797 TTC Fusion Nail

K060290 Shoulder Fixation System

K060294 Diaphyseal Plate

K893512 Cannulated Bone Screw

K103001 Rockwood Clavicle Pin

K041157 Small Bone Fixation System

K960385 Kirschner Wires & Steinmann Pins

Indications for Use

The indications for use remain unchanged from the existing clearances.

Technological Characteristics

The technological characteristics of the devices that are the subject of this submission remain unchanged from the predicates in terms of design, material and performance.

Summary of Substantial Equivalence

The products that are the subject of this submission are equivalent to the predicates. The technological characteristics are identical. Based on testing per AAMI TIR 12 and ANSI/AAMI ST79, the recommended steam sterilization parameters have been updated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration 10903 New Hampshire Avenue Document Mail Center – WO66-0609 Silver Spring, MD 20993-0002

DePuy orthopaedics, Incorporated % Ms. Suzana Otano Regulatory Affairs Project Manager 700 Orthopaedics Drive Warsaw, Indiana 46581-0988

MAR 1 2 2012

Re: K111663

Trade/Device Name: DePuy Internal Fixation Systems

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and

accessories

Regulatory Class: Class II

Product Code: HRS, HWC, HTN, KTT, LXT, HSB, JDW, HTY

Dated: February 2, 2012 Received: February 3, 2012

Dear Ms. Otano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Director

Division of Surgical, Orthopedic, and Restorative Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

510(k) Number: ((1)663

Device Name: TTC Fusion Nail

Indications For Use:

Intended for use in intramedullary fixation of supracondylar fractures of the femur, including those with severe comminution and intraarticular involvement, osteoporosis, nonunions, malunions, pathologic and fractures proximal to total knee arthroplasty or prosthesis. The TTC Fusion Nail is also indicated for use in tibiotalocalcaneal fusions and treatment of trauma to the hindfoot and distal tibia. Indications include: revision after failed ankle arthrodesis with subtalar involvement, absent talus (tibio calcaneal arthrodesis); post traumatic/primary arthrosis involving both ankle and subtalar joints; a rheumatoid hindfoot; avascular necrosis of the talus; previously infected arthrosis, second degree; failed total arthroplasty.

Prescription UseX	AND/OR	Over-the-Counter	
(Per 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111663

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- ,	510(k) Number:	1(11169)	•		
	Device Name:	Small Bone Loc	ked Platir	ıg System	
	Indications For U	<u>se</u> :			
	fusions, reconstruct foot, wrist, ankle, fi particularly in osted pediatric patients (a	stabilization and fixation tions (osteotomy) and n nger, toe, humerus, olec openic bone. The system adolescents [>12 – 21 yo ohyseal plates in skeleta	on-unions of the cranon, clavicle m can be used ears of age]),	he bones of the han e, scapula and pelvi I in both adult and where the implant w	nd, is,
	iption Use X I CFR 801 Subpart	AND/OR		-Counter 801 Subpart C)	
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510(k) Number: (< 11/643

Device Name: TTC Fusion Nail

Indications For Use:

Intended for use in tibiocalcaneal fusions and treatment of trauma to the hindfoot and distal tibia. Indications include: revision after failed ankle arthrodesis with subtalar involvement; absent talus (tibiocalcaneal arthrodesis); post traumatic or primary arthrosis involving both ankle and subtalar joints; rheumatoid hindfoot; avascular necrosis of the talus; previously infected arthrosis, second degree; failed total ankle arthroplasty. Indications also include non-union ankle arthrodesis; osteoarthritis; post-traumatic and degenerative arthritis; neuroarthropathy or neuropathic ankle deformity; neuromuscular disease with severe deformity and Charcot foot.

Prescription Use X	AND/OR	Over-the-Counter
(Per 21 CFR 801 Subpart D)	•	(21 CFR 801 Subpart C)

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510(k) Number <u>KUI (6(03</u>

510(k) Number:	16111693
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Device Name: Spider Plate

Indications For Use:

- Fixation of metaphyseal fractures of the distal tibia
- Proximal metaphyseal tibial fractures
- Calcaneus fractures
- Proximal humeral head/shaft fractures
- Distal femur fracture comminuted shaft fractures
- Fixation of soft tissue, such as tendon and ligaments, to bone

Prescription Use X (Per 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter(21 CFR 801 Subpart C)
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510(k) Number K111663

Division of Surgical, Orthopedic,

and Restorative Devices

510(k) Number:	K111663

Device Name: Reconstruction & Straight Plate

Indications For Use:

Small bone plates (3.5mm):

For intra-articular distal tibial fractures and those of the humeral head; for fractures of the fibula, lateral malleolus, metatarsals and metacarpals, olecranon and distal humerus; for application to the palmar surface of the distal radius and fractures of the olecranon and distal tibia; for application to the dorsum of the distal radius; fractures of the calcaneus; fractures of the radius and ulna; for pelvic and acetabular reconstructive surgery

Large bone plates (4.5, 6.5mm):

For use on the tibia, femur and humerus; for use on the anterior aspect of the distal tibia; for use as a tension band on the proximal humerus and as a buttress on the medial tibial plateau; for use as a buttress on the lateral tibial plateau; for use on fractures of the pelvis and acetabulum; for fractures of the distal humerus; for use as a tension band plate on the radius, ulna and fibula

Prescription UseX	AND/OR	Over-the-Counter	
Per 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)	

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510(k) Number 1C111663

<u>510(k) Number</u> :	K111 63		
<u>Device Name</u> :	TiMax Medial Pilo	on Plate	
Indications For Us	<u>se</u> :		
	stal tibial intraarticular fract ional distal extraarticular sl		r fractures,
December Hoo.	AND/OR	Over-the-Counter	
Prescription Use X (Per 21 CFR 801 Subpart		(21 CFR 801 Subpart C	;)
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<u>510(k) Number</u> :	1<111663			
<u>Device Name</u> :	TiMax Meta	Plate		
Indications For Us	<u>se</u> :			
Distal intra-articular humerus fractures	tibia fractures; p	roximal tibi	a fractures; proxi	mal and distal
		•		
Prescription Use X (Per 21 CFR 801 Subpart	_	ND/OR	Over-the-Count (21 CFR 801 St	
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510(k) Nu	mber KIIIde	3	.	

510(k) Number:	KIII 0P3	
<u>Device Name</u> :	100 Degree Tub	oular Plate
Indications For U	se:	
distal humerus and	d humeral head; applicat	netatarsals and metacarpals, olecranon, tion to the dorsum of the distal radius; ular distal tibial fractures
		. •
Prescription Use X (Per 21 CFR 801 Subpar	AND/OR t D)	Over-the-Counter (21 CFR 801 Subpart C)
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	orative Devices	
510(k) N	umber <u> </u>	

<u>510(k) Number</u> :	K111663	
Device Name:	Universal Recons	struction Plate
<u>Indications For Us</u>	<u>se</u> :	
humerus, acetabulu	um and pelvis. intended for use in the fo	of the clavicle, scapula, distal
		•
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		•
Prescription Use X (Per 21 CFR 801 Subpart	AND/OR D)	Over-the-Counter (21 CFR 801 Subpart C)
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510(k) Number KIII 663

510(k) Number:	111663		
Device Name: A	natomic Locked	l Plating System	
Indications For Use:		· ·	
	olecranon, metacarpa	and non-unions of the clavicle, I, metatarsal, malleolus, tibia, fibula,	
Prescription Use X (Per 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter (21 CFR 801 Subpart C)	
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510(k) Number 111663

	510(k) Number:	K111663		
	<u>Device Name</u> :	Fracture and Fus	ısion Plating System	
	Indications For Us	<u>se</u> :		
·	fusions, reconstructions, wrist, ankle, fit particularly in osteo pediatric patients (a	tions (osteotomy) and no nger, toe, humerus, olect openic bone. The system	n of fractures, revision procedures non-unions of the bones of the har cranon, clavicle, scapula and pelv m can be used in both adult and rears of age]), where the implant wally immature patients.	nd, is,
	cription Use X 21 CFR 801 Subpart	AND/OR :D)	Over-the-Counter (21 CFR 801 Subpart C)	
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	510(k) Number	KIIIlele3		

KIII 663 510(k) Number: LCL and Fusion Plating System **Device Name:** Indications For Use: Intended for use in stabilization and fixation of fractures, revision procedures, fusions, reconstructions (osteotomy) and non-unions of the bones of the hand, foot, wrist, ankle, finger, toe, humerus, olecranon, clavicle, scapula and pelvis, particularly in osteopenic bone. The system can be used in both adult and pediatric patients (adolescents [>12 - 21 years of age]), where the implant would not cross open epiphyseal plates in skeletally immature patients. Prescription Use X AND/OR Over-the-Counter_ (21 CFR 801 Subpart C) (Per 21 CFR 801 Subpart D) (PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE) (Division Sign-Off) Division of Surgical, Orthopedic, and Restorative Devices Page 1 of 1

510(k) Number KIII (do 3

<u>510(k) Number</u> :	K11663	
<u>Device Name</u> :	Proximal Tibia Lo	cking Plating System
Indications For Us	<u>e</u> :	
and fractures of the depression, medial	proximal tibia, including si wedge, bicondylar combin	nies, malunions, osteopenic bone imple, comminuted, lateral wedge, nation of lateral wedge and associated shaft fractures.
		·
Prescription Use X (Per 21 CFR 801 Subpart	_ AND/OR D)	Over-the-Counter(21 CFR 801 Subpart C)
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	510(k) Number:	K111663	
	<u>Device Name</u> :	Small Bone Lockii	ng Plating System
	procedures, joint fu	— d fixation of small bone frag sion and reconstructions of us, scapula, finger, toe, pel	gments in fresh fractures, revision f small bones of the hand, foot, vis and craniomaxillofacial skeleton,
	ription Use X 21 CFR 801 Subpart	AND/OR D)	Over-the-Counter (21 CFR 801 Subpart C)
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510(k) Number ___

510(k) Number:	Ku1063		
<u>Device Name</u> :	Sterile DVR		
Indications For Us	<u>se</u> :		
Intended for fixation	n of fractures and osteoto	mies involving the distal r	radius
		•	
	·		
rescription Use X Per 21 CFR 801 Subpart	_ .	Over-the-Counter (21 CFR 801 Subpart	<u>C)</u>
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and Re	estorative Devices	•	Page 1 of 1
510(k)	Number XIII663		

510(k) Number:	K111067
<u>Device Name</u> :	Locking Anatomic and Composite Plating System
Indications For Us	<u>se</u> :
metatarsals and me	ures, osteotomies and non-unions of the fibula, malleolus, etacarpals, olecranon, clavicle, scapula, distal humerus and us, ulna and distal tibia, particularly in osteopenic bone.
Prescription Use X (Per 21 CFR 801 Subpart	AND/OR Over-the-Counter D) (21 CFR 801 Subpart C)
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<u>510(k) Number</u> :	1(11/63		
<u>Device Name</u> :	Anterolateral a System	and Medial Locking P	lating
Indications For I	<u>Use</u> :		
The Medial Locki fractures, high extraarticular sha	medial malleolar fract	pilon fractures: distal tibial tures, low boot type rota	intraarticular tional distal
The Anterolateral fractures, proxima	Locking Plates are indical tibia fractures and pro	cated for distal intraarticular t eximal and distal humerus frac	ibia ctures.
Prescription Use X (Per 21 CFR 801 Subpa	AND/O	OVER-the-Counter (21 CFR 801 Subpart	<u>C)</u>
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510(k) N	umber KIII (63		

Device Name:	Large Fragment L (Locking Broad ar	•	ystem
Indications For U	<u>se</u> :		
Fixation of various use in fixation of os malunions and oste	long bones, such as the hu steopenic bone and fixation eotomies.	ımerus, femur and tibia and stabilization of nor	. Also for n-unions,
		· .	
Prescription Use X (Per 21 CFR 801 Subpart	AND/OR t D)	Over-the-Counter (21 CFR 801 Subpar	t C)
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510(k) Number:

<u>510(k) Number</u> :	K1116C3		
<u>Device Name</u> :	Small Fragment L	_ocking Plating Sy	/stem
Indications For Us	<u>·</u> <u>se</u> :		·
Intended for fixation scapula, olecranon osteopenic bone.	n of fractures, osteotomies , humerus, radius, ulna, p	s and non-unions of the clelvis, distal tibia, fibula, pa	avicle, articularly in
Prescription Use X (Per 21 CFR 801 Subpart	AND/OR D)	Over-the-Counter (21 CFR 801 Subpart	<u>C)</u>
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510(k) N	lumber KIII663		

	OTOTIC ITALIA		
	<u>Device Name</u> :	Fragment Plate S	ystem
	Indications For Us	<u>se</u> :	•
	fragments in fresh f	ractures, revision procedu ne hand, foot, wrist, ankle,	oilization and fixation of small bone res, joint fusion and reconstruction humerus, scapula, finger, toe, pelvis
	cription Use X 21 CFR 801 Subpart	_ AND/OR D)	Over-the-Counter (21 CFR 801 Subpart C)
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	510(k) No	umber KIN 663	

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<u>510(k) Number</u> :	1(11)663	
Device Name:	Polyax Locked Pl	lating System
Indications For Us	<u>se</u> :	·
osteotomies of the Fixation (ORIF) rep proximal tibia include such as simple combined bicondylar, combined for the fixed proximal tibic proxi	distal femur and proximal air of closed and open fra- ding, but not limited to the nminuted, lateral wedge, d	on of malunions, non-unions, and tibia and Open Reduction Internal ctures of the distal femur and following: periarticular fractures, lepression, medial wedge, d depression fractures with a fractures.
Prescription Use X (Per 21 CFR 801 Subpart	_ AND/OR D)	Over-the-Counter (21 CFR 801 Subpart C)
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510(k) Number 111663

<u>510(k) Number</u> :	KIII (63		
<u>Device Name</u> :	Multidirectional T	hreaded Peg	
Indications For U	<u>se</u> :		
Intended for the fix	cation of fractures and osteo	otomies involving the dis	tal radius
	•		
	•		
Prescription Use X (Per 21 CFR 801 Subpar	AND/OR t D)	Over-the-Counter (21 CFR 801 Subpart	C)
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510(k) N	umber KIU663		

	510(k) Number:	K111663	
	<u>Device Name</u> :	Distal Volar Radiu System	s Anatomical Plate
	Indications For U	<u>se</u> :	
	Intended for the fix	ation of fractures and osteo	tomies involving the distal radius
Preso (Per 2	cription Use X 21 CFR 801 Subpar	AND/OR t D)	Over-the-Counter(21 CFR 801 Subpart C)
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510(k) <u>Number</u> :	K111663
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PERI II Knee Fracture System Device Name:

Indications For Use:

Intended for use in fracture fixation cases requiring open reduction internal fixation (ORIF) for closed and open fractures of the distal femur and proximal tibia including repair of non-unions, malunions and fractures including but not limited to simple comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression and fractures with associated shaft fractures

Prescription Use X Per 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter(21 CFR 801 Subpart C)
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	510(k) Number: KIII663	
	Device Name: Calcaneal Peri-Articular Plate	
	Indications For Use:	
	Designed to assist the surgeon in the management of intra-articular frathe calcaneus, extra-articular fractures of the calcaneus	actures of
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	ription Use X AND/OR Over-the-Counter (21 CFR 801 Subpart II)	C)
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	(Division-Sign-Off) Division of Surgical, Orthopedic, and Restorative Devices	Page 1 of 1
	510(k) Number KIII (263	

<u>510(k) Number</u> :	K111663		
<u>Device Name</u> :	TK2 Hip Screw	System	
Indications For Us	<u>se</u> :		
the level of the less Appropriate utilizati	res of the proximal fem er trochanter, as well a on of this device ultima eatient's particular situa	as proximal femoral ately depends on th	l osteotomies.
			·
Prescription Use X (Per 21 CFR 801 Subpart	AND/O D)	R Over-the-Cou (21 CFR 801	
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510(k) Number KII 1663

510(k) Number:	((1)663	
<u>Device Name</u> :	Trochanteric Side	Plate
Indications For U	<u>se</u> :	
Internal fixation of	hip fractures	·
Prescription Use X (Per 21 CFR 801 Subpar	AND/OR t D)	Over-the-Counter (21 CFR 801 Subpart C)
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Divis	sion Sign-Off) sion of Surgical, Orthopedic, Restorative Devices	Page 1 of 1
510(1	Number KIII 663	

<u>510(k) Number</u> :	K111613				
Device Name:	Supracor	ndylar Pla	te		
Indications For U	<u>se</u> :			,	
Internal fixation of	hip fractures				
•		: ·			·
Prescription Use X (Per 21 CFR 801 Subpart	<u> </u>	AND/OR	Over-the-Co (21 CFR 80		
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5	10(k) Number_	K111662	<u> </u>		

<u>510(k) Number</u> :	K111663		
<u>Device Name</u> :	Captured Hip Scre	ew	
Indications For Us	<u>se</u> :		
Internal fixation of I	hip fractures		
	·		
•			•
Prescription Use X (Per 21 CFR 801 Subpart	_	Over-the-Counter(21 CFR 801 Subpart	C)
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an	d Restorative Devices		Page 1 of 1

510(k) Number:	Killer)	
<u>Device Name</u> :	6.5mm Solid Canc	ellous Bone Screw
Indications For Us	<u>se</u> :	
	of this device shall include e femur, tibia, ulna, radius,	fixation of the pelvis and of the long humerus and fibula.
· .		
Prescription Use X (Per 21 CFR 801 Subpart	AND/OR D)	Over-the-Counter(21 CFR 801 Subpart C)
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510(k) Number KIIILe63	·

510(k) Number:	1(11)(6)	•
Device Name:	8.0mm Cannulated	d Cancellous Bone Screw
Indications For Use	<u>⊋</u> :	
Fracture fixation of lo	ong bones (femur, tibia, su ot and ankle and os calcis	ubcapital fracture of the hip, pelvic , olecranon)
	·	
Prescription Use X (Per 21 CFR 801 Subpart I	AND/OR O)	Over-the-Counter (21 CFR 801 Subpart C)
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<u>510(k) Number</u> :	1(11/663		
<u>Device Name</u> :	Titanium Mini-Pla	ting System	
Indications For Us	<u>se</u> :		
	lofacial fractures or for oth ned by the surgeon	er small bone fractures (fra	cture
		·	
Prescription Use X (Per 21 CFR 801 Subpart	AND/OR D)	Over-the-Counter(21 CFR 801 Subpart C)	- .
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510(k) Number:	(111 6 13		
Device Name:	Cannulated Corti	cal Bone Screw	
Indications For U	<u>se</u> :		
Fracture fixation of	long bones		
·		•	
Prescription Use X Per 21 CFR 801 Subpart	AND/OR t D)	Over-the-Counter (21 CFR 801 Subpart C)	_
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510(k) N	lumber KIII 663		

<u>510(k) Number</u> :	K11/66)	·	
<u>Device Name</u> :	Cannulated Self-t Screw	apping Cancellous l	Bone
Indications For Us	<u>se</u> :		
Fracture fixation of	long bones	· .	
		• .	
Prescription Use X (Per 21 CFR 801 Subpart	AND/OR D)	Over-the-Counter(21 CFR 801 Subpart C)	.
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and Rest	orative Devices	Pa	age 1 of 1
510(k) N	lumber KIII (de 3		

510(K) Number.			
<u>Device Name</u> :	Cannulated Self-ta Screw	apping Cortical E	3one
Indications For U	lse:		
	dic conditions and fractures pping cortical bone screws	that would benefit from	the use of
		•	
			•
Prescription Use X Per 21 CFR 801 Subpa	AND/OR rt D)	Over-the-Counter (21 CFR 801 Subpar	t C)
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	mber KIILLOG3		Page 1 of 1
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	510(k) Number:	K111,093			·
•	<u>Device Name</u> :	Cancello	us Bone S	Screw	
	Indications For Us	se:			•
	Internal fixation of l condylar fractures plateau.				
	cription Use X 21 CFR 801 Subpart	D)	AND/OR	Over-the-Counter (21 CFR 801 Sub	
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	510(k) N	umber_KIII	(e/e 3		Page 1 of

<u>510(k) Number</u> :	1641663		
<u>Device Name</u> :	Diaphyseal Plate		
<u>Indications For Us</u>	<u>e</u> :		
		s and non-unions of the cl distal tibia, fibula, particul	
Prescription Use X (Per 21 CFR 801 Subpart	_ AND/OR D)	Over-the-Counter_ (21 CFR 801 Subpart	<u>C)</u>
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and Restorati	ve Devices		Page 1 of 1
510(k) Numb	per KIIIQQ3	_	

<u>510(k) Number</u> :	K11166)		
Device Name:	Shoulder Fixation	ı System	
Indications For Us	se:		
Intended for fracture the proximal humer		ns, osteotomies and non-uni	ons of
	·		
Prescription Use X (Per 21 CFR 801 Subpart	AND/OR D)	Over-the-Counter_ (21 CFR 801 Subpart C)	_
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510(k)	Number KILL 663		

<u>510(k) Number</u> :	K111663	·
<u>Device Name</u> :	Cannulated Bone	Screw
Indications For U	<u>se</u> :	
Intended for use ov cannulated screw i	ver a guide pin for fracture s intended to be inserted i	fixation in cancellous bone. The nto pre-drilled bone.
•		
	·	
·		
Prescription Use X Per 21 CFR 801 Subpar	_	Over-the-Counter (21 CFR 801 Subpart C)
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510(k) Nur	mber <u>XIII (663</u>	·

510(k) Number:	K111663

Device Name: Tibial Nail

Indications For Use:

Intended for bone fixation in the management of fracture and reconstructive surgeries.

Non-weight bearing bone fixation is indicated in the following conditions:

- Transverse, oblique, spiral, segmental and comminuted fractures;
- · Fractures with bone loss and bone transport;
- · Open fractures, pathologic fractures;
- · Corrective osteotomies;
- · Pseudarthrosis of the tibial shaft;
- Nonunions, malunions, metaphyseal and epiphyseal fractures.

Prescription UseX		AND/OR	Over-the-Counter
(Per 21 CFR 801 Subpart D)	•		(21 CFR 801 Subpart C)

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<u>510(k) Number</u> :	K11663		
Device Name:	Washer		
Indications For Us	<u>se</u> :		
Intended to be use	d in conjunction with bone	screws	
·			
Prescription Use X (Per 21 CFR 801 Subpart	AND/OR D)	Over-the-Counter(21 CFR 801 Subpart (C)
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510(k)	Number Kll (Ole 3		

<u>510(k) Number</u> :	1(111663	
<u>Device Name</u> :	Trochanteric Nail	·
Indications For Us	<u>se</u> :	
pertrochanteric frac fractures and comb is additionally indic fractures, patholog diaphyseal areas, I	ctures, intertrochanteric fra inations of these fractures ated to treat pertrochanter c fractures in osteoporotic	al fractures of the femur including actures, high subtrochanteric s. The Trochanteric Long Nail system ric fractures associated with shaft bone of the trochanteric and ures, ipsilateral femoral fractures, and revision procedures.
Prescription Use X (Per 21 CFR 801 Subpart	AND/OR D)	Over-the-Counter (21 CFR 801 Subpart C)
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510(k) Number K (1063

510(k) Number:	4111663	
		

Device Name: Universal Humeral Nail

Indications For Use:

Indicated for open and closed fracture patterns, humeral shaft fractures, fractures of the proximal and distal metaphysis, comminuted fractures of the humerus with small medullary canals, fracture non-unions and mal-unions, pathological fractures, floating elbow.

D	AND/OR	Over-the-Counter
Prescription Use X	AND/OR	
(Per 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

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510(k) Number 111(063

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	510(k) Number:	1(11/663	·		
	Device Name:	Proximal	Humeral	Nail	·
	Indications For U	se:			,
	intended as a quid	e to normal he t intended to r	aling and are eplace norma	actures. These implants not intended as a guide I body structure or bear e healing.	to normal
				·	
	ription Use X 21 CFR 801 Subpar	<u>t</u> D)	AND/OR	Over-the-Counter (21 CFR 801 Subpart	C)
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	510(k	x) Number <u>/</u>	111663		Page 1 of 1

<u>510(k) Number</u> :	K11/613
	

Device Name: Universal and Troch Entry Nail

Indications For Use:

Intended to treat proximal, middle and distal third fractures, severely comminuted shaft fractures extending beyond the isthmus, spiral, long oblique and segmental fractures, non-unions and malunions, lengthening of the bone, fractures with bone loss, bi-lateral fractures, pseudoarthrosis of the femoral shaft, supracondylar fractures, subtrochanteric fractures, with or without involvement of lesser trochanter, subtrochanteric/intertrochanteric combination fractures, ipsilateral femoral shaft and neck fractures, stable and unstable proximal fractures of the femur, including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, pertrochanteric features associated with shaft fractures, pathologic fractures in osteoporotic bone of the trohchanteric and diaphyseal areas, proximal or distal non-unions and malunions, leg length discrepancies secondary to femoral inequality, femur reconstruction following tumor resection, stable femoral fractures without necessity for interlocking, long subtrochanteric fractures, and revision procedures involving the replacement of implanted hardware. In addition to the above indications, the Universal NAIL, when used in the retrograde mode, is also indicated for treatment of femoral shaft fractures in obese or multiple trauma patients and supracondylar fractures, including those with severe, extra-articular comminution and/or intra-articular involvement, osteoporosis, non-unions, malunions, pathologic fractures, and those proximal to total knee prosthesis.

Prescription UseX (Per 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter (21 CFR 801 Subpart C)
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510(k) Number 1611(663

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	<u>510(k) Number</u> :	(11) 663		
	<u>Device Name</u> :	Rockwood Clavicl	e Pin	
	Indications For Us	<u>se</u> :		
	Intended to be use clavicle.	d to repair an acute fracture	e, malunion or non-union	of the
				,
	cription Use X 21 CFR 801 Subpart	AND/OR : D)	Over-the-Counter (21 CFR 801 Subpart	
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		ision Sign-Off) sion of Surgical, Orthopedic, Restorative Devices		Page 1 of 1
	510(1	k) Number <u>XIIIQ63</u>		
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510(k) Number:	1(11663	<u>-</u>	
<u>Device Name</u> :	Small Bone Fi	xation System	
Indications For U For the fixation of the metacarpals are bones of the foot.	extra-articular fracture	es of the long bones of the hand in	including ırsal
Prescription Use X Per 21 CFR 801 Subpar	AND/0 t D)	OR Over-the-Counter (21 CFR 801 Subpart C)	
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510(k) Numb	per_10111663		

<u>510(k) Number</u> :	K111663	-		·
<u>Device Name</u> :	Kirschner Wir	es & Stein	mann Pins	
Indications For U	se:			·
Fixation of bone fra other implants or ir the skeletal system	actures, for bone reco nplantation through th n.	nstructions, as ne skin so that	guide pins for in traction may be a	sertion of applied to
Prescription Use X (Per 21 CFR 801 Subpart	AND/ : D)		ne-Counter R 801 Subpart C	
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